

Remarks

Claims 34-49 are pending in the application. Claim 37 has been withdrawn from consideration. Claims 34-36 and 38-49 stand rejected.

Claims 39 and 40 have been canceled by the present Amendment. Claims 34-38 and 41-43 have been amended. Claim 34 has been amended to remove recitation of language relating to “modified” protein allergens and to add the clause “the composition being formulated for rectal, vaginal, nasal, oral, buccal, or mucosal delivery.” Claim 34 has also been amended in accordance with the Examiner’s suggestion in a sister case, *i.e.*, to recite “protein allergens.” Claims 35-38 and 41-43 have been amended to correct the antecedent basis for these claims.

No new matter has been added by the present Amendment. Applicant specifically reserves the right to pursue the subject matter of the canceled or amended claims in a related application. The present Amendment is introduced for the *sole* purpose of furthering prosecution. Applicant respectfully requests reexamination and reconsideration of the case in light of the present Amendment and the following Remarks. Each of the rejections levied in the Office Action is addressed individually below.

Amendments to the specification

The specification has been amended to include material incorporated by reference from U.S. Serial No. 09/141,220 (the ‘220 application). In particular, the specification has been amended to include a corrected Sequence Listing incorporated by reference from the ‘220 application.

Please note that SEQ ID NOs: 1-3 as originally presented in the present case have been renumbered as SEQ ID NOs: 82-84 in order to maintain continuity of numbering of SEQ ID NOs. Thus, SEQ ID NOs: 82-84 of the presently amended specification correspond to SEQ ID NOs: 1-3, respectively, of the present application as originally filed.

Priority

The present application is a divisional of and contains an identical disclosure to U.S. patent application serial number 09/731,375, filed December 6, 2000 (“the ‘375 application”). The ‘375 application claims priority to U.S. provisional patent application serial number 60/195,035, filed April 6, 2000 (“the ‘035 application”). On pages 2-3 of the Office Action, the

Examiner alleges that the claims are not entitled to the priority date of the '035 application, but instead, that "[t]he filing date of instant claims 34-36 and 39-49 is deemed to be the filing date of instant application 10/725,323, which is December 4, 2003. The instant claim 38 is given the priority of 09/731,375 filed December 6, 2000" (Office Action, page 3, second full paragraph). The Examiner makes this determination on the grounds that neither the '135 nor the '035 application adequately enables or describes dead *E. coli* containing modified Ara h 6 (*see* Office Action, page 3, second full paragraph). Applicant respectfully disagrees with the Examiner's determination of priority.

As an initial matter, Applicant notes that the present claims do not contain language regarding "modified" protein allergens.

Moreover, Applicant notes that *any claim* in the present application is entitled to *at least* priority back to the '135 application. Indeed, the present application is a divisional of and *contains an identical disclosure* to the '135 application. Since the present application and the '135 application both have identical disclosures, any claim in the present application *must* have priority *at least* as far back as the filing date of the '135 application, *i.e.*, December 6, 2000.

In addition, Applicant respectfully submits that support for protein allergen Ara h 6 *does*, in fact, extend all the way back to the '035 application (*see* page 52 of the '035 application as filed). Thus, Applicant respectfully submits that the present claims should be granted priority back to the filing date of the '035 application, *i.e.*, April 6, 2000.

Notwithstanding the foregoing, Applicant further submits that the Examiner's determination of priority for the claims in the present application is inherently flawed. In particular, Applicant notes that the present claims are directed to a *genus* of compositions, and that the *genus* is fully described and enabled in both the '035 and '135 applications. Moreover, the species elected by Applicant for initiation of the Examiner's search of the genus is for the Examiner's *convenience* in performing that search. The election of species does *not* change the fact that the present claims are, in fact, *genus* claims, and that the Examiner should look to the *genus* – *not the particular elected species* – when determining the priority to which the genus claim is entitled. In the present determination of priority, however, the Examiner impermissibly looked to the particular elected species when assessing priority. Applicant respectfully requests that the Examiner perform a proper assessment of priority in light of the comments above and grant the present application priority back to the '035 application, *i.e.*, back to April 6, 2000.

Objection to the Specification

The Examiner has objected to the disclosure on the ground that the numbering of the SEQ ID NOs in the specification is mismatched with the Sequence Listing in several specific instances. Applicant has submitted herewith an amendment to enter material incorporated by reference from U.S. Serial No. 09/141,220 (the '220 application) into the present application. In particular, the specification has been amended to include a corrected Sequence Listing incorporated by reference from the '220 application. Applicant respectfully submits that the numbering of SEQ ID NOs in the corrected Sequence Listing is consistent with that found in the Specification and Drawing. Applicant respectfully requests that the rejection be removed.

Rejection under 35 U.S.C. § 112, first paragraph, for alleged lack of written description and enablement

Claims 34-36 and 38-49 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. The Examiner alleges that, “[a]t the time of filing, applicants are [*sic*; were] not in possession of any dead *E. coli* encapsulated therein any modified peanut allergen Ara h6 whose amino acid sequence has any one or more mutation in any IgE site, any deletions, any substitutions of any amino acid or any addition within any IgE binding site of the wild type peanut allergen Ara h6” (Office Action, page 7, third full paragraph).

In addition, claims 34-36 and 38-49 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. The Examiner alleges that, “the specification . . . **does not** reasonably provide enablement for a composition comprising dead *E. coli*. [*sic*; *E. coli*] comprising any modified peanut allergen such as Ara h1, Ara h2 and Ara h3 or Ara h6 . . . for treating or *preventing* undesirable allergic reactions and anaphylactic allergic reactions to peanut in a subject” (Office Action, page 11, third full paragraph; emphasis in original).

Applicant respectfully disagrees with both of the Examiner’s rejections under § 112, first paragraph.

As an initial matter, Applicant notes that the present claims do not include the particular sequence modification language to which the Examiner objects. The present claims are directed to *new formulations of known materials*. As set forth in the specification, substantial numbers of protein allergens were known at the time when the present application was filed, and the present

inventors demonstrated for the very first time that these known allergens could be made surprisingly useful in novel and inventive formulations. According to the MPEP, “[i]nformation which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).” MPEP § 2163. The present claims are not drawn to the allergens themselves, but instead, *new formulations that contain protein allergens*. The specification provides abundant support for and description of such formulations.

For all of these reasons, Applicant respectfully submits that the rejection is both mooted by the present Amendment and irrelevant to the present claims.

Obviousness-Type Double Patenting

The Examiner has levied a *provisional* obviousness-type double patenting rejection, asserting that claims 34-36 and 38-49 pending in the present application are not patentably distinct from claims 34-45 of co-pending U.S.S.N. 10/728,051. Applicant respectfully refrains from commenting on this rejection until such time as it matures into an *actual* rejection.

The Examiner has levied a *provisional* obviousness-type double patenting rejection, asserting that claims 34-36 and 38-49 pending in the present application are not patentably distinct from claims 34-45 of co-pending U.S.S.N. 12/843,739. Applicant respectfully refrains from commenting on this rejection until such time as it matures into an *actual* rejection.

Rejection under 35 U.S.C. § 103(a) as allegedly being obvious

Claims 34-36, 38-40, 43-44, and 48-49 stand rejected under 35 U.S.C. § 103(a) on the ground that they are unpatentable over U.S. Patent Application Publication Number 2005/0175630 (“the ‘630 publication”) in view of U.S. Patent Number 6,187,311 (“the ‘311 patent”) and PCT Application Publication Number WO 97/24139 (“the ‘139 publication”) or Rabjohn *et al.* (1999, *J. Clin. Invest.*, 103:535-42) (“Rabjohn”).

Claims 45 and 47 stand rejected under 35 U.S.C. § 103(a) on the ground that they are unpatentable over the ‘630 publication in view of the ‘311 patent and the ‘139 publication or Rabjohn, and further in view of U.S. Patent Number 6,004,815 (“the ‘815 patent”).

Claim 42 stands rejected under 35 U.S.C. § 103(a) on the ground that they are unpatentable over the '630 publication in view of the '311 patent and the '139 publication or Rabjohn, and further in view of Leclerc *et al.* (1990, *J. Immunol.*, 144:3174-82).

Applicant respectfully submits that all of these rejections are improper § 103(a) rejections, as the primary reference, *i.e.*, the '630 publication, is not available as prior art to the present application.

Indeed, as printed on the face of the '630 publication and confirmed in the USPTO's Patent Application Information Retrieval (PAIR) database, the *earliest* priority claim for the '630 publication is U.S. provisional patent application serial number 60/532,786, which was filed on December 23, 2003. In contrast, Applicant submits that the earliest priority date for the present application is *earlier than* December 23, 2003. Indeed, even if the Examiner were to persist in not acknowledging the priority claim for the present application, the *actual filing date* of the present application is December 4, 2003, which is *clearly* before the earliest priority date of the '630 application. Moreover, although Applicant disagreed with the Examiner's determination of priority for the present application, Applicant notes that even the Examiner herself recognized that the present application must *at least* be entitled to priority as early as the filing date of the present case, *i.e.*, December 4, 2003 ("[t]he filing date of instant claims 34-36 and 39-49 is deemed to be the filing date of instant application 10/725,323, which is December 4, 2003. The instant claim 38 is given the priority of 09/731,375 filed December 6, 2000." Office Action, page 3, second full paragraph). Applicant, therefore, respectfully submits that the '630 publication – which is the *primary reference* upon which *all* § 103 rejections are based – is clearly not available as prior art against the present application. Applicant respectfully requests that the rejection be withdrawn.

Conclusion

For all of the reasons set forth above, each of the rejections in this case should be removed and the application should proceed to allowance. A Notice to that effect is respectfully requested.

If, at any time, it appears that a phone discussion would be helpful, the undersigned would greatly appreciate the opportunity to discuss such issues at the Examiner's convenience. The undersigned can be contacted at (617) 248-4903.

Respectfully submitted,

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